What is claimed is:

1. In a stented graft that can alternately include a compact configuration having a first diameter and an expanded configuration having a greater diameter, comprising, in combination:

- at least one stent formed in a generally cylindrical shape having an outer surface and a hollow bore extending longitudinally therethrough, wherein said stent can alternately exist in a compact configuration having a first diameter, and an expanded configuration having a greater diameter and a plurality of lateral openings; and,
- a flexible, porous, biocompatible tubular elastomer covering having a first end, a second end, an outer surface and a hollow bore that extends longitudinally therethrough to define an inner surface;

said stent being deployed coaxially within said hollow bore of said covering such that said inner surface of said tubular covering is in contact with said outer surface of said stent;

the improvement wherein said stent comprises a plurality of elements, wherein each said element comprises an undulating linear shape formed into a generally cylindrical configuration having a cylinder axis generally aligned on the axis of said hollow bore, and wherein each said element is connected to an adjacent neighbor element by at least one linear connector.

2. The stented graft of claim 1, wherein said plurality of elements comprises a spiral.

3. The stented graft of claim 1, wherein at least one said connector is substantially circumferentially offset from an adjacent neighbor connector.

4. The stented graft of claim 3, wherein said circumferentially offset connectors form a helical array.

5. The stented graft of claim 1, wherein at least one said connector is not substantially circumferentially offset from an adjacent neighbor connector.

6. The stented graft of claim 1, wherein said undulating linear shape is a generally zigzag shape comprising a plurality of zigs having tips and a plurality of zags having tips, wherein said tip of each said zig of each element and the nearest said tip of each said zig of an adjacent neighbor element generally lie in a plane passing through the axis of said hollow bore, and wherein said tip of at least one said zig of each element and at least one said nearest said tip of a zig of an adjacent neighbor are connected by one said linear connector.

7. The stented graft of claim 1, wherein said undulating linear shape is a sinusoidal shape having a plurality of peaks and a plurality of valleys, wherein

each said peak of each element and each said valley of an adjacent neighbor lie generally in a common plane passing through the axis of said hollow bore, and wherein at least one said peak of each element and said valley of an adjacent neighbor lying generally in said common plane are connected by one said linear connector.

8. The stented graft of claim 1, wherein each said linear connector has a length dimension generally parallel to the axis of said hollow bore, and a width and depth dimension, and wherein said length dimension is greater than said width dimension and said length dimension is greater than said depth dimension.

9. The stented graft of claim 8, wherein said length dimension is about 3 to 10 times greater than said width dimension, and said length dimension is about 3 to 10 times greater than said depth dimension.

10. The stented graft according to claim 1, wherein said stent and said elastomer are anchored to each other by means for anchoring.

11. The tubular stented graft according to claim 10, wherein said means for anchoring comprise protrusions of said covering that fixedly protrude into said lateral openings in said stent.

12. The stented graft of claim 1 wherein said elastomer covering is formed of an elastomer selected from the group consisting of polytetrafluoroethylene, fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl chloride, polypropylene, polyethylene terephthalate, broad fluoride; and, other biocompatible plastics.

13. The stented graft of claim 1 wherein said elastomer covering is formed of expanded, sintered PTFE tape, said tape having been wound about the outer surface of said stent to create said covering thereon.

14. The stented graft of claim 12, wherein said polytetrafluoroethylene is expanded polytetrafluoroethylene having fibrils.

15. The stented graft of claim 14, wherein said fibrils measure up to about 300 μ in length.

16. The stented graft of claim 14, wherein said fibrils measure up to about 200 μ in length.

17. The stented graft of claim 14, wherein said fibrils measure up to about 100 μ in length.

18. The stented graft of claim 14, wherein said fibrils measure up to about 50 μ in length.

19. The stented graft of claim 14, wherein said fibrils measure up to about 5 μ in length.

20. The stented graft of claim 13 wherein said tape has a width of less than about 1 inch.

21. The stented graft of claim 13 wherein said tape has a thickness of less than 0.015 inch (0.038 cm.) and wherein said tape is wound about said stent in overlapping fashion, such that said elastomer covering comprises 1 to 10 layers of said tape.

22. The stented graft of claim 13 wherein said tape is helically wrapped about said stent.

23. The stented graft of claim 13 wherein said tape has a width of 0.5 inches (1.27 cm), and wherein said tape is helically wrapped such that 6-8 revolutions of tape are applied per longitudinal inch (2.54 cm.) of said stented graft.

24. The stented graft of claim 13 wherein said tape is helically wrapped alternately in a first direction and then in the opposite direction.

25. The stented graft of claim 24 further comprising 8 layers of said tape.

26. The stented graft of claim 1 wherein said stent is a self-expanding stent.

27. The stented graft of claim 26, wherein said self-expanding stent comprises a shape memory alloy that can alternately exist in a first and a second crystalline state, wherein said stent assumes a radially expanded configuration when said shape memory alloy is in said first crystalline state, and a radially compact configuration when said shape memory alloy is in said second crystalline state.

28. The stented graft of claim 1 wherein said stent is a pressure-expandable stent.

29. The stented graft of claim 1 wherein said stent is formed of a metal alloy comprising at least two elements selected from the group consisting of iron, cobalt, chromium, nickel, titanium, niobium, and molybdenum.

30. The stented graft of claim 27 wherein said shape memory alloy comprises at least about 51% to about 59% nickel and the remainder comprising titanium.

31. The stented graft of claim 27 wherein said shape memory alloy comprises about 0.25% chromium, at least about 51% to about 59% nickel, and the remainder comprising titanium.

32. The stented graft of claim 1 wherein said covering has a thickness of less than 0.1 inch (0.25 cm.).

33. The stented graft of claim 13 wherein said PTFE tape has a thickness of less than 0.015 inches (0.038 cm.), said tape being wrapped about said stent in overlapping fashion so as to form said covering.

34. The stented graft of claim 13 wherein said PTFE tape has a density of less than 1.6 g/cc.

35. The stented graft of claim 13 wherein said covering has a thickness of less than 0.1 inch (0.25 cm.) and said PTFE tape has a density of less than 1.6 g/cc.

36. The stented graft of claim 1 wherein said stent further comprises a polymer coating formed on said stent.

37. The stented graft of claim 36 wherein said polymer coating formed on said stent is of a polymer material selected from the group consisting of polytetrafluoroethylene, fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl chloride, polypropylene, polyethylene terephthalate, polyvinylidene fluoride, and, other biocompatible plastics.

38. The stented graft of claim 36 wherein said polymer coating was applied to said stent by the steps of:

- immersing said stent in a liquid polymer dispersion;
- removing said stent from said liquid polymer dispersion; and,
- drying said liquid polymer dispersion that has remained on said stent,

whereby said polymer coating is formed on said stent.

39. The stented graft of claim 36 wherein said polymer coating is formed by electron beam deposition.

40. The stented graft of claim 36 wherein said tubular covering is adherent to said polymer coating.

41. A method for the treatment of cardiovascular disease, comprising implanting the stented graft of claim 1 in a patient in need of such treatment wherein said

implantation is effective to ameliorate one or more of the symptoms of said cardiovascular disease.

42. An article of manufacture, comprising packaging material and the stented graft of claim 1 contained within the packaging material, wherein said stented graft is effective for implantation in a patient afflicted with cardiovascular disease, and the packaging material includes a label that indicates that said device is effective for said implantation.

43. In a stented graft that can alternately include a compact configuration having a first diameter and an expanded configuration having a greater diameter, comprising, in combination:

- at least one stent formed in a generally cylindrical shape having an outer surface and a hollow bore extending longitudinally therethrough to form an inner surface, wherein said stent can alternately exist in a compact configuration having a first diameter, and an expanded configuration having a greater diameter and a plurality of lateral openings; and,
- a tubular inner graft formed of an elastomer, said tubular inner graft having an outer surface and an inner surface, said tubular inner graft being deployed coaxially within said hollow bore of said stent; whereby said outer surface of said tubular inner graft is in contact with said inner surface of said stent;

the improvement wherein said stent comprises a plurality of elements, wherein each said element comprises an undulating linear shape formed into a generally cylindrical configuration having a cylinder axis generally aligned on the axis of said hollow bore, and wherein each said element is connected to an adjacent neighbor element by at least one linear connector.

44. The stented graft of claim 43, wherein said plurality of elements comprises a spiral.

45. The stented graft of claim 43, wherein at least one said connector is substantially circumferentially offset from an adjacent neighbor connector.

46. The stented graft of claim 45, wherein said circumferentially offset connectors form a helical array.

47. The stented graft of claim 43, wherein at least one said connector is not substantially circumferentially offset from an adjacent neighbor connector.

48. The stented graft of claim 43, wherein said undulating linear shape is a generally zigzag shape comprising a plurality of zigs having tips and a plurality of zags having tips, wherein said tip of each said zig of each element and the nearest said tip of each said zig of an adjacent neighbor element generally lie in a plane passing through the axis of said hollow bore, and

wherein said tip of at least one said zig of each element and at least one said nearest said tip of a zig of an adjacent neighbor are connected by one said linear connector.

49. The stented graft of claim 43, wherein said undulating linear shape is a sinusoidal shape having a plurality of peaks and a plurality of valleys, wherein each said peak of each element and each said valley of an adjacent neighbor lie generally in a common plane passing through the axis of said hollow bore, and wherein at least one said peak of each element and said valley of an adjacent neighbor lying generally in said plane are connected by one said linear connector.

50. The stented graft of claim 43, wherein each said linear connector has a length dimension generally parallel to the axis of said hollow bore, and a width and depth dimension, and wherein said length dimension is greater than said width dimension and said length dimension is greater than said depth dimension.

51. The stented graft of claim 50, wherein said length dimension is about 3 to 10 times greater than said width dimension, and said length dimension is about 3 to 10 times greater than said depth dimension.

52. The stented graft according to claim 43, wherein said stent and said elastomer are anchored to each other by means for anchoring.

53. The stented graft according to claim 43, wherein said means for anchoring comprise protrusions of said outer surface that fixedly protrude into said lateral openings in said stent.

54. The stented graft of claim 43 wherein said elastomer is selected from the group consisting of polytetrafluoroethylene, fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl chloride, polypropylene, polyethylene terephthalate, broad fluoride; and, other biocompatible plastics.

55. The stented graft of claim 54, wherein said polytetrafluoroethylene is expanded polytetrafluoroethylene having fibrils.

56. The stented graft of claim 55, wherein said fibrils measure up to about 300 μ in length.

57. The stented graft of claim 55, wherein said fibrils measure up to about 200 μ in length.

58. The stented graft of claim 55, wherein said fibrils measure up to about 100 μ in length.

59. The stented graft of claim 55, wherein said fibrils measure up to about 50 μ in length.

60. The stented graft of claim 55, wherein said fibrils measure up to about 5 μ in length.

61. The stented graft of claim 43 wherein said stent is a self-expanding stent.

62. The stented graft of claim 61, wherein said self-expanding stent comprises a shape memory alloy that can alternately exist in a first and a second crystalline state, wherein said stent assumes a radially expanded configuration when said shape memory alloy is in said first crystalline state, and a radially compact configuration when said shape memory alloy is in said second crystalline state.

63. The stented graft of claim 43 wherein said stent is a pressure-expandable stent.

64. The stented graft of claim 43 wherein said stent is formed of a metal alloy comprising at least two elements selected from the group consisting of iron, cobalt, chromium, nickel, titanium, niobium, and molybdenum.

65. The stented graft of claim 62 wherein said shape memory alloy comprises at least about 51% to about 59% nickel and the remainder comprising titanium.

66. The stented graft of claim 62 wherein said shape memory alloy comprises about 0.25% chromium, at least about 51% to about 59% nickel, and the remainder comprising titanium.

67. The stented graft of claim 43 wherein said stent further comprises a polymer coating formed on said stent.

68. The stented graft of claim 67 wherein the polymer coating formed on said stent is of a polymer material selected from the group consisting of polytetrafluoroethylene, fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl chloride, polypropylene, polyethylene terephthalate, polyvinylidene fluoride, and, other biocompatible plastics.

69. The stented graft of claim 67 wherein said polymer coating was applied to said stent by the steps of:

- immersing said stent in a liquid polymer dispersion;
- removing said stent from said liquid polymer dispersion; and,
- drying said liquid polymer dispersion that has remained on said stent,

whereby said polymer coating is formed on said stent.

70. The stented graft of claim 67 wherein said polymer coating is formed by electron beam deposition.

71. The stented graft of claim 43 wherein said elastomer is adherent to said polymer coating.

72. A method for the treatment of cardiovascular disease, comprising implanting the stented graft of claim 43 in a patient in need of such treatment wherein said implantation is effective to ameliorate one or more of the symptoms of said cardiovascular disease.

73. An article of manufacture, comprising packaging material and the stented graft of claim 43 contained within the packaging material, wherein said stented graft is effective for implantation in a patient afflicted with cardiovascular disease, and the packaging material includes a label that indicates that said device is effective for said implantation.

74. An improved tubular stented graft which is alternately deployable in a radially compact configuration having a first diameter and a radially expanded configuration having a second diameter, said stented graft comprising:

- a stent comprising:
  - at least one member formed in a generally cylindrical shape having an outer surface and a hollow bore which extends longitudinally therethrough to define an inner surface;
  - said stent being initially radially collapsible to a diameter which is substantially equal to said first diameter of the stented graft, and subsequently radially expandable to a diameter which is substantially equal to said second diameter of the stented graft; and,
  - a plurality of lateral openings existing in said stent when said stent is at its radially expanded second diameter;
- a continuous, tubular PTFE covering formed on said stent, said PTFE covering comprising:
  - a tubular inner base graft formed of expanded, sintered PTFE, said tubular base graft having an outer surface and an inner surface, said tubular base graft being deployed coaxially within the hollow bore of said stent such that the outer surface of the tubular base graft is in contact with the inner surface of the stent, and the inner surface of said tubular base graft thereby defining a luminal passageway through the stented graft; and,

- a tubular outer layer formed of expanded, sintered PTFE tape which has a width of less than about 1 inch, said tape having been wound about the outer surface of said stent to create said tubular outer layer thereon, such that said stent is captured between said outer layer and said tubular base graft;

said tubular outer layer being attached to said tubular base graft, through said lateral openings in said stent, to thereby form an integrally stented, continuous PTFE tube which is alternately disposable in said radially compact configuration of said first diameter and said radially expanded configuration of said second diameter;

the improvement wherein said stent comprises a plurality of elements, wherein each said element comprises an undulating linear shape formed into a generally cylindrical configuration having a cylinder axis generally aligned on the axis of said hollow bore, and wherein each said element is connected to an adjacent neighbor element by at least one linear connector.

75. The stented graft of claim 74, wherein said plurality of elements comprises a spiral.

76. The stented graft of claim 74, wherein at least one said connector is substantially circumferentially offset from an adjacent neighbor connector.

77. The stented graft of claim 76, wherein said circumferentially offset connectors form a helical array.

78. The stented graft of claim 74, wherein at least one said connector is not substantially circumferentially offset from an adjacent neighbor connector.

79. The stented graft of claim 74, wherein said undulating linear shape is a generally zigzag shape comprising a plurality of zigs having tips and a plurality of zags having tips, wherein said tip of each said zig of each element and the nearest said tip of each said zig of an adjacent neighbor element generally lie in a plane passing through the axis of said hollow bore, and wherein said tip of at least one said zig of each element and at least one said nearest said tip of a zig of an adjacent neighbor are connected by one said linear connector.

80. The stented graft of claim 74, wherein said undulating linear shape is a sinusoidal shape having a plurality of peaks and a plurality of valleys, wherein each said peak of each element and each said valley of an adjacent neighbor generally lie in a plane passing through the axis of said hollow bore, and wherein at least one said peak of each element and said valley of an adjacent neighbor lying generally in said plane are connected by one said linear connector.

81. The stented graft of claim 74, wherein each said linear connector has a length dimension generally parallel to the axis of said hollow bore, and a width and depth dimension, and wherein said length dimension is greater than said width dimension and said length dimension is greater than said depth dimension.

82. The stented graft of claim 81, wherein said length dimension is about 3 to 10 times greater than said width dimension, and said length dimension is about 3 to 10 times greater than said depth dimension.

83. The stented graft of claim 74 wherein said PTFE is replaced by an elastomer selected from the group consisting of fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl chloride, polypropylene, polyethylene terephthalate, broad fluoride; and, other biocompatible plastics.

84. The stented graft of claim 74 wherein said PTFE covering is formed of expanded, sintered PTFE tape, said tape having been wound about the outer surface of said stent to create said covering thereon.

85. The stented graft of claim 74, wherein said PTFE is expanded polytetrafluoroethylene having fibrils.

86. The stented graft of claim 85, wherein said fibrils measure up to about 300 μ in length.

87. The stented graft of claim 85, wherein said fibrils measure up to about 200 μ in length.

88. The stented graft of claim 85, wherein said fibrils measure up to about 100 μ in length.

89. The stented graft of claim 85, wherein said fibrils measure up to about 50 μ in length.

90. The stented graft of claim 85, wherein said fibrils measure up to about 5 μ in length.

91. The stented graft of claim 84 wherein said tape has a width of less than about 1 inch (2.54 cm.).

92. The stented graft of claim 84 wherein said tape has a thickness of less than 0.015 inch (0.038 cm.) and wherein said tape is wound about said stent in overlapping fashion, such that said elastomer covering comprises 1 to 10 layers of said tape.

93. The stented graft of claim 84 wherein said tape is helically wrapped about said stent.

94. The stented graft of claim 84 wherein said tape has a width of 0.5 inches (1.27 cm), and wherein said tape is helically wrapped such that 6-8 revolutions of tape are applied per longitudinal inch (2.54 cm.) of said stented graft.

95. The stented graft of claim 84 wherein said tape is helically wrapped alternately in a first direction and then in the opposite direction.

96. The stented graft of claim 95 further comprising 8 layers of said tape.

97. The stented graft of claim 74 wherein said stent is a self-expanding stent.

98. The stented graft of claim 97, wherein said self-expanding stent comprises a shape memory alloy that can alternately exist in a first and a second crystalline state, wherein said stent assumes a radially expanded configuration when said shape memory alloy is in said first crystalline state, and a radially compact configuration when said shape memory alloy is in said second crystalline state.

99. The stented graft of claim 74 wherein said stent is a pressure-expandable stent.

100. The stented graft of claim 97 wherein said stent is formed of a metal alloy comprising at least two elements selected from the group consisting of iron, cobalt, chromium, nickel, titanium, niobium, and molybdenum.

101. The stented graft of claim 98 wherein said shape memory alloy comprises at least about 51% to about 59% nickel and the remainder comprising titanium.

102. The stented graft of claim 98 wherein said shape memory alloy comprises about 0.25% chromium, at least about 51% to about 59% nickel, and the remainder comprising titanium.

103. The stented graft of claim 74 wherein said covering has a thickness of less than 0.1 inch (0.25 cm.).

104. The stented graft of claim 84 wherein said PTFE tape has a thickness of less than 0.015 inches (0.038 cm.), said tape being wrapped about said stent in overlapping fashion so as to form said covering.

105. The stented graft of claim 84 wherein said PTFE tape has a density of less than 1.6 g/cc.

106. The stented graft of claim 84 wherein said covering has a thickness of less than 0.1 inch (0.25 cm.) and the PTFE tape has a density of less than 1.6 g/cc.

107. The stented graft of claim 74 wherein said stent further comprises a polymer coating formed on said stent.

108. The stented graft of claim 107 wherein said polymer coating formed on said stent is of a polymer material selected from the group consisting of polytetrafluoroethylene, fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl chloride, polypropylene, polyethylene terephthalate, polyvinylidene fluoride, and, other biocompatible plastics.

109. The stented graft of claim 107 wherein said polymer coating was applied to said stent by the steps of:

- immersing said stent in a liquid polymer dispersion;
- removing said stent from said liquid polymer dispersion; and,
- drying said liquid polymer dispersion that has remained on said stent,

whereby said polymer coating is formed on said stent.

110. The stented graft of claim 107 wherein said polymer coating is formed by electron beam deposition.

111. The stented graft of claim 107 wherein said tubular covering is adherent to said polymer coating.

112. A method for the treatment of cardiovascular disease, comprising implanting the stented graft of claim 74 in a patient in need of such treatment wherein said implantation is effective to ameliorate one or more of the symptoms of said cardiovascular disease.

113. An article of manufacture, comprising packaging material and the stented graft of claim 74 contained within the packaging material, wherein said stented graft is effective for implantation in a patient afflicted with cardiovascular disease, and the packaging material includes a label that indicates that said device is effective for said implantation.